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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,216	04/10/2007	Yasuhiko Takahashi	600630-58US	5928

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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT	PAPER NUMBER
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1636

NOTIFICATION DATE	DELIVERY MODE
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03/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@panitchlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/593,216	TAKAHASHI ET AL.	
	Examiner	Art Unit	
	NANCY VOGEL	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 11/30/09 is acknowledged. The traversal is on the ground(s) that the groups share a special technical feature. This is not found persuasive because the technical feature shared by the groups is not novel over the prior art, since the technical feature in common is a sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein. This is disclosed by the references cited below. Therefore the groups do not share a special technical feature that is novel.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims encompass a nucleic acid as it exists in nature. The claims encompass a chromosome as it occurs in nature.

.Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, 8, 9, 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

A written description of an invention involving a chemical genus, like a description of a chemical species, “requires a precise definition, such as by structure, formula, [or] chemical name,” of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is

unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...”) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not a sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP § 2163.

The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include: (1) Actual reduction to practice, (2) Disclosure of drawings or structural chemical formulas, (3) Sufficient relevant identifying characteristics (such as: i. Complete structure, ii. Partial structure, iii. Physical and/or chemical properties, iv. Functional characteristics when coupled with a known or disclosed, and correlation between function and

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structure), (4) Method of making the claimed invention, (5) Level of skill and knowledge in the art, and (6) Predictability in the art.

“Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.”

MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a genus of polynucleotides which comprise a nucleotide sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein, without any limitation on the origin of the G-protein, which control the transcription of the a downstream polynucleotide.

Initially it is noted that claims must be given their broadest reasonable interpretation in light of the instant specification during examination. Therefore, it is noted that the base claim 1 on which the claims depend recite a polynucleotide comprising **a nucleotide sequence** of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein. It is noted that any two nucleotides, at least, which are a part of the recited promoter region, would read on "a sequence of a promoter region..." . Therefore the claims would encompass numerous polynucleotides with the only limitation being having at least 2 nucleotides (“a polynucleotide”) in common with the disclosed mouse promoter of the alpha subunit Gm1 of trimeric G-protein.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is

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unquestionable that claim(s) 4, 5, 8, 9, 13 are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are numerous to any polynucleotide which has promoter activity and which has at least 2 polynucleotides in common with the disclosed SEQ ID NO:1, which is the only Gm1 alpha subunit promoter disclosed.

Specifically, the claims lack written description because it is clear that it would required experimentation to determine which of the virtually infinite numbers of polynucleotides meeting the structural limitation, which has promoter activity.

Although the claims recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. While having written description of SEQ ID NO: 1, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 6, 7, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter which consists of the polynucleotide whose sequence is shown in SEQ ID NO:1 does not reasonably provide enablement for polynucleotides having a nucleotide sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to polynucleotides having a nucleotide sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein. There is no functional limitation to the polynucleotides recited in the claims. Applicants have

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taught a promoter having the sequence shown in SEQ ID NO:1. The claims encompass an unreasonable number of inoperative polynucleotides, which the skilled artisan would not know how to use. There are limited working examples of the polynucleotide having 100% identity to SEQ ID NO:1 as a promoter. The claim recites a polynucleotide comprising **“a nucleotide sequence of a promoter region”** and therefore encompasses any polynucleotide comprising only 2 nucleotides of the disclosed mouse promoter of the gene encoding alpha subunit Gm1 of trimeric G-protein, i.e. SEQ ID NO:1. There is a lack of guidance of which polynucleotides could be altered and retain function. The skilled artisan would not know how to use the encompassed non-identical polynucleotides on the basis of teachings in the prior art or specification unless they possessed the promoter function disclosed in the instant specification.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the lack of knowledge about function(s) of encompassed polynucleotides encompassed by the claims, the limited working examples, the lack of direction or guidance for using polynucleotides that are not identical to SEQ ID NO:1, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7, are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al., (EST result 1, Accession number AZ660697, Dec. 14, 2000).

Dunn et al. disclose a polynucleotide comprising a nucleotide sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein whose sequence is shown in SEQ ID NO:1. The reference discloses a plasmid comprising the polynucleotide (E. coli strain XL10-Gold). See SCORE search result file.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Isak (GenEmbl result 5, Locus and Accession number AC140207, Nov. 27, 2003).

Isak discloses a polynucleotide comprising a nucleotide sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein whose sequence is shown in SEQ ID NO:1. The reference discloses a plasmid comprising the polynucleotide (RPCI-24 BAC library). Since the clone is a genomic clone, the downstream gene is present, and constitutes a “reporter” gene since any gene encoding an assayable product (i.e. mRNA or protein product) would constitute a reporter gene. The promoter in the clone would control the transcription or expression of the reporter gene downstream.

Claims 1-8, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Holtzman et al. (J. Biol. Chem. 266, 3, 1763-1771, 1991).

Holtzman et al. disclose a polynucleotide comprising a nucleotide sequence of a promoter region of a gene encoding alpha subunit Gm1 of trimeric G-protein whose sequence is shown in SEQ ID NO:1. Since the claim reads "a nucleotide sequence of a promoter region " it would encompass any promoter of a G protein having at least 2 nucleotides in common. The reference discloses a plasmid comprising the polynucleotide (see abstract, see pages 176-1767). The reference discloses the promoter with a reporter gene, luciferase, downstream, and kits comprising transformed cells and means for assaying the reporter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/

Primary Examiner, Art Unit 1636

NV

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